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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,702	07/22/2003	Charles D. Shermer	45337	4912
7590 01/23/2007 John E. Holmes Roylance, Abrams, Berdo & Goodman, L.L.P. Suite 600 1300 19th Street, N.W. Washington, DC 20036			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/623,702

Applicant(s)

SHERMER ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/21/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

This action is in response to applicant amendments submitted 21 December 2006.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Grau (US 3,048,171).

Regarding claims 1,6,7,12 Grau teaches a fluid reservoir (10) having a flexible wall (13); a patient needle (44) in selective communication with the reservoir, a Belleville spring (21) having a central aperture (in 23) and a pin (25) engageable with the central aperture.

Regarding claims 2,8, and 13 there is a tactile indication that the pin is disengaged from the central aperture of the Belleville spring.

Regarding claims 3-5, 9-11, 14-17,19, and 20, disengagement of the pin with the Belleville spring occurs when a user operates a push button/pull handle (26), and includes removing a pushbutton guard (27) so that the pushbutton can be operated.

3. Claims 1-4,6-10,12-15, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sage et al (US 5,957,895).

Regarding claims 1,6,7, and 12 Sage teaches an infusion device comprising a fluid reservoir (50) having at least one flexible wall (102 or 104), a needle in selective

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communication with the reservoir (76), a Belleville spring (102 or 104) with a central aperture (57), and a pin (63).

Regarding claims 2,8, and 13 there is a tactile indication that the pin is disengaged from the central aperture of the Belleville spring. See Figures 5 and 6.

Regarding claims 3,4,9,10,14,15,17,19 and 20, disengagement of the pin with the Belleville spring occurs when a user operates a push button/pull handle (42)

Allowable Subject Matter

4. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a patch-like infusion device wherein disengagement of a pin with the central aperture of a Belleville spring occurs when an operation comprising the removal of a pull handle operably connected to the pin is performed, in combination with the other limitations of the claims.

Response to Arguments

6. Applicant's arguments filed 21 December 2006 have been fully considered but they are not persuasive. Applicant's arguments regarding the Sage reference previously applied to claims 1-11 discusses the interpretation of "pin" 63 of Sage. The examiner believes that element 63 meets the limitations of the pin as claimed by the applicants. The pin moves into engagement with the central aperture (57) of a Belleville spring to allow the Belleville spring to apply pressure the reservoir (Figs 5 and 6). Without

engagement of 63 with the central aperture, the pressure of the fluid inside the reservoir would prevent the Belleville springs from compressing and no fluid would be delivered to the patient. The fact that pin 63 is also part of fluid transfer means 54 is irrelevant since it has the structure claimed by the applicant.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth MacNeil
1/19/07

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons